B. A. I. Administrative Notice 4 Issued February 3, 1940.

Effective on and after February 15, 1940.



UNITED STATES DEPARTMENT OF AGRICULTURE

BUREAU OF ANIMAL INDUSTRY

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Sec. 112.6[1] Trade labels; permission for use. Trade labels represented by those bearing Bureau stamp "Approved" shall not be affixed or otherwise applied to containers of veterinary biologics after June 30, 1940, nor shall such products so labeled be marketed by any licensee after December 31, 1940. Specimen labels to which no exceptions are taken by the Bureau will be stamped hereafter "Use Permitted Until Further Notice."

Sec. 112.7 Trade labels; directions for handling and use of product. Each trade label shall bear adequate directions for proper use of the product. The quantity of the contents of each immediate or true container must be shown on each label in units, grams, milligrams, or cubic centimeters. Such labels shall also give instructions to protect the product from light and keep it at a temperature of not more than 45° F. Trade labels for multiple-dose containers shall bear a warning that all the product should be used at the time the container is first opened. Trade labels and circular matter shall bear no statement, design, or device which may deceive the purchaser or which is false or misleading in any particular.

Sec. 112.8 Trade labels names or terms. Names or terms on trade labels shall conform to the following list:

ANTITOXINS

Anaerobic antitoxin
Antivenin
Botulinus antitoxin
Tetanus antitoxin

SERUMS

Antianthrax serum
Antibacterial serum:
    Bovine
    Canine
    Equine
    Feline
Antiencephalomyelitis serum:
    Eastern
    Western
    Eastern and western
Anti-feline-distemper serum
Anti-hemorrhagic-septicemia serum

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[1] The numbering of the sections of B. A. I. administrative notices conforms to the numbering in title 9, chapter I, of The Code of Federal Regulations.

Porcine
Antiblackleg serum
Anti-bronchisepticus-bacillus serum
Anti-canine-distemper serum
Anti-hog-cholera serum
Antistreptococcus serum
Anti-swine-erysipelas serum
Gonadin serum
Normal serum

## AGGRESSINS

Blackleg cultural aggressin
Blackleg natural aggressin
Hemorrhagic-septicemia aggressin

## DIAGNOSTICS

Avian tuberculin
Johnin
Mallein
Pullorin
Tuberculin

## TOXOIDS

Staphylococcus aureus toxoid
Tetanus toxoid

## VACCINES AND VIRUSES

Anthrax spore vaccine
Blackleg cultural vaccine
Blackleg tissue vaccine
Brucella abortus vaccine
Canine-distemper vaccine
Canine-distemper virus
Encephalomyelitis vaccine:
Eastern
Western
Eastern and western
Fowl-laryngotracheitis vaccine
Fowl-pox vaccine
Hog-cholera vaccine
Hog-cholera virus
Ovine-ecthyma vaccine
Pigeon-pox vaccine
Rabies vaccine
Swine-erysipelas vaccine (export only)
Wart vaccine.

## BACTERINS

Anthrax bacterin
Autogenous bacterin
Avisepticus-gallinarum bacterin
Blackleg bacterin
Bronchisepticus-bacillus bacterin
Bronchisepticus-streptococcus bacterin
Clostridium chauvei-septicus bacterin
Clostridium chauvei-welchii bacterin (export only)
Clostridium hemolyticum bacterin
Colon-bacillus bacterin
Felisepticus-bacillus bacterin
Gallinarum-typhimurium bacterin
Hemorrhagic-septicemia bacterin
Listerella monocytogenes bacterin
Pasteurella avicida bacterin
Salmonella abortivoequina bacterin
Staphylococcus bacterin
Staphylococcus-streptococcus bacterin
Streptococcus bacterin

MIXED BACTERINS

Mixed bacterin:
Avian
Bovine
Canine
Equine

Mixed bacterin:
Feline
Lepine
Ovine
Porcine

Sec. 114.5 Outlines of methods of production. Outlines of methods of producing and testing each biologic under license shall be filed with the Bureau by the licensee. These outlines shall describe fully the entire process of producing and testing each product. No batch of product that is worthless, contaminated, dangerous, or harmful may be marketed. Tests that are applicable and necessary to prevent the marketing of such a product shall be made by the licensee. These tests include sterility, safety, potency, agglutination titer, complement fixation titer, and the like. Outlines to which no exceptions are taken by the Bureau will be stamped hereafter "Filed with the Bureau of Animal Industry (date)," in lieu of "Accepted," and copies will be returned to the licensee. Such outlines must be followed by the licensee until an amended outline has been filed with the Bureau. Exceptions may be taken by the Bureau to these filed outlines at any time.

Sec. 114.29 Mixing the product. Each batch or serial of product shall be mixed thoroughly in a single container and be constantly agitated during subsequent bottling operations. Serial numbers in sequence, with any other marking that may be necessary for ready comprehension, shall be used to identify each batch with the records of preparation and labeling.

Sec. 116.3 Records and reports of tests. Records of production, testing, and the like must be completed by the licensee before any part of a batch of any product may be marketed. Copies of such tests records as the inspector in charge is authorized to receive must be delivered to him before any part of a batch of product is removed from the premises.

This notice, which is based on B. A. I. Order 276, dated August 18, 1922, shall be effective on and after February 15, 1940. The exact citations are as follows:

Section 112.6 -- Reg. 12, Sec. 2, par. 7.
Section 112.7 -- Reg. 12, sec. 2, pars. 1 to 4.
Section 112.8 -- Reg. 12, sec. 2, par. 7.
Section 114.5 -- Reg. 14, sec. 1.
Section 114.29 -- Reg. 14, sec. 1.
Section 116.3 -- Reg. 16, sec. 1, pars. 1 and 2.

All previous requirements are superseded to the extent that they conflict with this notice. Section 114.5 supersedes Circular Letter No. 1681, dated October 6, 1930.

J. R. Mohler,
Chief of Bureau.